RESULTWORKS

Transforming Strategy. Delivering Success.

Transformations

QUARTERLY NEWSLETTER   VOLUME 9, ISSUE 1

OF SPECIAL INTEREST:

- **Knowledge management is more than just a technology play**

- **Strategic roadmaps provide a common language for addressing an organization's needs and a great tool to communicate consistently**

- **Tools and approaches to improve your ELN selection and implementation process**

- **Re-engineering processes facilitates and improves solution selection**

INSIDE THIS ISSUE:

R&D KNOWLEDGE MANAGEMENT - TECHNOLOGY INITIATIVE OR BUSINESS FUNDAMENTAL?

Ask people about knowledge management and the responses are amazingly diverse:

"We have an R&D Wiki."
"We are currently exploring a new technology."
"We tried that a few years ago and it failed."
"That's our translational medicine program."
"We're building an R&D wide data repository."
"We're developing a search engine that can tap all of our data repositories."

Technology driven responses are the norm. From an executive perspective, knowledge management might be better defined as the collective information and know-how needed to carry out the business. How it is done and where knowledge resides depends heavily on or-

ganizational maturity.

Across the industry from large Pharma to small Biotechs, the way companies manage their knowledge is as varied as a palette. Assessments routinely identify inconsistent processes, informal systems, research by spreadsheet, results documented in MS Office tools, and ultimately data and reports archived in PDF or paper systems. None of these address tacit knowledge that is not explicitly stored. What is knowledge management in this context? The needs of any organization depend on their present state, including organizational construct, processes used to advance work, technology, and often specific people employed to execute on the business plan.

Knowledge Management Framework

All three of these taken together with the people involved characterize the know-how to carry out the business of R&D. Presumably the organization, business process, and technology have been optimized for any given R&D area.

ELN BEST PRACTICES AND PITFALLS

Many organizations today are planning to select and deploy Electronic Laboratory Notebook (ELN) solutions to their R&D organizations. Solutions are expected to replace existing departmental systems and in most cases will replace paper notebooks with a searchable repository of research information and corporate intellectual property. The ELN promises to save information in legible,

searchable form while eliminating the collection, scanning and storage of paper notebooks. Some organizations even eliminate the witnessing process since the ELN system can keep legally defensible records and audit trails showing exactly when information was known and reduced to practice. This series of articles addresses some best practices and pitfalls often encountered by organizations

throughout the lifecycle of an ELN implementation.

Part I: Establish a Strategic Vision for the ELN

Best Practice: Before starting the ELN selection process, develop a strategic five to ten year vision of the role of the ELN in the organization and how it fits with other systems that will be

R&D KNOWLEDGE MANAGEMENT (CONTINUED FROM PAGE 1)

Frequently that is not the case. External drivers change the business. Organizations change to respond to the business drivers and changes in people as they ebb and flow. Critical changes in either one often require business process changes. Technology that supported the business years ago may be out of date. As the business evolves, know-how evolves often embedded in the people responsible for generating results. Fundamental to an effective business is balancing knowledge and know-how among people, the organization, business processes, and yes, technology.

Drivers for Knowledge Management

Small organizations are typically focused on day to day concerns about data and results management. They are focused on the immediate project, study, or experiment, tests required, analyses required, generating reports, and moving on to the next activity. Even large organizations tend to operate this same way and experience

many of the same issues. They are a collection of smaller organizations with some process, some systems, more interdependencies, and more challenges.

As R&D organizations try to do more with less, they need to adapt. Business drivers point to the need for improved knowledge management which will:

- Achieve shorter new product development cycles

- Increase knowledge content and access across R&D

- Manage the proliferation of information in complex R&D environments

- Facilitate and manage organizational innovation and learning

- Leverage expertise across the organization

- Increase networking among employees and external partners with the objective of improving information flow

- Manage intellectual capital and assets as the workforce changes

Knowledge Management Sponsorship

With R&D organizations heads down on identifying new compounds, completing study reports, formulating new products, or generating other results, senior management must sponsor initiatives to change course. Knowledge management should be

a focus of any R&D strategy. That strategy should encompass organizational dynamics, optimized business processes, and well placed technology. With clear objectives and alignment, knowledge management can:

- Unleash business process efficiencies

- Accelerate the pace of change

- Facilitate the retention of knowledge during staff attrition (voluntary or involuntary)

- Support globalization and global integration

- Enable achievement of new business insights.

Conclusions

Knowledge management is more than the latest technology applied as an informatics initiative. More broadly, it is a framework that includes people, process, and technology; the collective know-how to conduct the business. R&D leaders need to embrace knowledge management as part of their business strategy. Doing so will enable clearer trade-offs and decisions regarding business processes, application of informatics solutions, as well as alignment of organizations. It is fundamental to the business of R&D.

"Overall I think the process was excellent. I was particularly impressed by how ResultWorks was able to get the team to reach consensus although not everyone agreed initially."

ELN BEST PRACTICES AND PITFALLS (CONTINUED FROM PAGE 1)

present such as workflow management, document management, laboratory information management, and scientific data management systems and repositories. Your ELN solution will likely fit on top these systems and tie them together. It may also be very important for future consideration to determine the value of integration between the ELN and these systems. Be sure this strategic vision is shared by senior

management from the business and IT.

 Pitfall: Avoid jumping into the ELN world before you know how the ELN must fit within your organization over the long run. Unlike some other software systems, the ELN should be a long term investment in preserving your intellectual property and boosting the productivity of your research organization. Jumping in too soon

will produce a lot of questions downstream related to use of your existing systems and may delay or derail approval and use of your selected ELN system.

In the next newsletter, Part II will tackle Defining Requirements for the ELN.

SELECTING A CLINICAL TRIAL MANAGEMENT SYSTEM—RE-ENGINEER YOUR PROCESSES FIRST!

Selecting a new Clinical Trials Management System (CTMS) for an organization holds the promise of better and timelier information sharing, more informed forecasting and planning, and better partner relationships. However, before you leap in it is a good idea to re-examine and re-engineer your current business processes.

Many organizations do not have an existing CTMS, and business processes have evolved around non-shared personal spreadsheets of data and informal communications. Those organizations who were early adopters of CTMS' have often customized their systems heavily, potentially embedding business processes that may no longer represent best practice.

Investing time upfront in business process analysis and process workflow modeling of the impacted business functions and interactions with customer groups provides the following benefits:

- Agree 'best practice' workflow for your organization

- Identify and eliminate redundant processes and supporting systems

- Get buy-in for implementation from all stake holder groups

- Understand data flow, eliminate data duplication and optimize data sharing

- Define the scope of operations that the CTMS will need to support

- Agreed process workflows directly support the development of User Requirements for the commercial solution selection process

Process re-engineering need not be a lengthy exercise. A typical evaluation, from zero to agreed new processes, may only need 8 – 9 weeks if a disciplined methodology is followed. ResultWorks' proven methodology includes the following steps:

- Identify the project team and conduct a formal kick off meeting with executive sponsor participation

- Conduct short teleconference or face-to-face interviews with key stakeholders to understand the current process, identify issues and gaps, and get input for future process improvements

- Develop end-to-end straw man 'to-be' processes (for situations where an existing CTMS is in place, 'as-is' processes may be developed to contrast before and after)

- Conduct a ResultSession^{SM} with the project team to review and adjust the new processes

- Document the new processes and conduct a final review with stakeholders and sponsors

ResultWorks' experience with CTMS selection has demonstrated the effectiveness and value of investing time in business process analysis and re-engineering as a first step in a CTMS selection process. By undertaking this upfront effort, the downstream user requirements and vendor request for proposal (RFP) package truly reflect the system requirements for an optimized process. This minimizes scope creep and unexpected requirements during implementation.

STRATEGY ROADMAP BRIDGES BUSINESS AND INFORMATICS OBJECTIVES

In today's environment of increasing competition, consolidation, and operational effectiveness, having a clear picture of where an organization wants to go is essential to success. By necessity, Life Sciences organizations need to transform themselves in a way that integrates change associated with business process, technology, knowledge management, and organizational dynamics. Because the environment is fast moving, the approach to transformation needs to be flexible and dynamic. The development of a living strategic roadmap provides an excellent tool to do this.

The strategic planning and roadmap process also serves as an excellent mechanism to both identify and communicate strategic objectives for an organization, while building buy-in to the plan. Developing buy-in is a critical success factor. To achieve the desired results, the effort must target the right approach, involve the right people, and provide an appropriate level of detail to elucidate intent, priority and direction. Additionally, it is critical to build strategic alignment within the team. Without appropriate scope definition at the onset, the effort can quickly become all things to all people and provide little real value to the business. Thus, having the right team, clearly defining expectations, and clarifying roles, responsibilities, and scope is essential to building alignment. This, in turn, requires strong executive sponsorship with a foundational vision for the future that is communicated to all participants.

Once the scope and team have been formed, they will work through a process to understand what is known (process, technology, etc.), envision what could be (idea generation without restraint), determine what should be (balancing the ideas with reality), perform a gap analysis, and translate that work into an agreed roadmap. The roadmap should take into consideration many aspects of the implementation that are often overlooked and provide a clear pathway to implementing needed change. This may include projects and work efforts centered on foundational, tactical, and strategic technology needs, changes to processes and associated standard operating procedures, work practices and guidelines, information management, knowledge management, change management, and organizational change.

If done well, the strategic roadmap will provide a common language for addressing future needs and will facilitate communication among functional areas within your organization. Further, it will provide a common reference for decision-making around operational project portfolios.

ABOUT RESULTWORKS

ResultWorks is a management consulting company which transforms business strategies for Life Science companies into successful technology and process optimization initiatives. Results are achieved through skilled facilitation and exceptional management leadership.

ResultWorks' ResultSession is the cornerstone of our methodology and promotes collaboration and rapid decision-making while balancing people, process and technology challenges.

To request additional information about ResultWorks, send us an email at marketing@resultworksllc.com or visit our website at www.resultworksllc.com .

TIME FOR A CHANGE OF PROCESS, SYSTEMS OR PROJECTS?

The IKEA Effect: When Labor Leads to Love

By Michael Norton, Harvard Business Publishing

"People place a disproportionately high value on products they had a hand in making. They'd rather buy their own amateurish origami than something made by a pro. The IKEA effect may explain why business managers keep failing projects alive: because of all of the time and effort they've invested."

This article is particularly relevant to Life Sciences at this time as it is increasingly evident that the industry will need to change how we've always done business to continue to thrive and not go the way of the automobile and other industries that failed to meet the challenge of change.

For the entire article **click here.**

In The News

Sampling of current client initiatives:
Global ELN Implementation Project
ELN Definition & Vendor Selection for Formulations
Discovery PK Process Assessment

Recent & upcoming appearances:
LabAutomation 2009
Bob O'Hara, Managing Partner, presented a paper entitled "ELN Implementations Expose and Generate Value from Knowledge Assets"

Bio-IT Conference April 27-29 in Boston
Come visit us at Booth #317!

45th DIA Annual Meeting in San Diego June 21-24.
Susan Butler, Managing Partner,
will present a paper entitled "Business Process Analysis Enables CTMS Definition and Selection Process."

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